O. Intermediate Sanctions (§§422.750 through 422.760)

As stated in the interim final rule, M+C organization actions that are subject to intermediate sanctions include those specified at §417.500 for contracts under section 1876 of the Act. The BBA also contained additional sanction authority not found in §417.500, which we have implemented in subpart O. Specifically, section 1857(g)(3) of the Act provides that the Secretary can impose intermediate sanctions and civil money penalties based on a finding that the grounds in section 1857(c)(2) of the Act for terminating a contract are met. These grounds for termination are reflected in §422.510(a), and are discussed in section II.K and II.N above. While intermediate sanctions based on the grounds for termination at §422.510 generally are imposed on the same terms as sanctions for the violations specified in §422.750(a), in the case of all grounds except a finding of fraud or abuse under §422.510(a)(4), HCFA, rather than the OIG, imposes civil money penalties.

We received 3 comments on subpart O.

Comment: A commenter contended that the intermediate sanctions provisions do not provide Medicare contracting organizations with sufficient appeal rights before intermediate sanctions are imposed. Another commenter argued that the Congress originally intended intermediate sanctions to be an intermediate step less severe than a termination, and that

instead suspension of payment for enrollees can be a worse penalty than termination. This commenter believes that the use of intermediate sanctions and civil money penalties has been incorporated as a program management tool, rather than an intermediate step to termination, which the commenter believes should follow sanctions.

Response: In the case of the imposition of a civil money penalty, extensive appeal rights are afforded, including the right to a hearing before the departmental appeals board (DAB). In the case of an "intermediate sanction," however, the entire point of this authority is to allow the Secretary to take swift action to respond to a finding of a serious violation of M+C requirements. Since the sanction is temporary, and only remains in place until corrective actions have been taken, elaborate appeal rights were not contemplated by the Congress, and would not be appropriate. The Congress has demonstrated in section 1857(h) of the Act that it knows how to require specific appeal rights when it wishes to do so. We believe that an M+C organization’s interests are sufficiently protected by giving the organization an opportunity to seek reconsideration of a decision to impose intermediate sanctions by demonstrating that the basis for the decision is incorrect, and giving the organization an opportunity to have the sanctions lifted when corrective action is taken. This approach is consistent with what is provided with

respect to intermediate sanctions in the nursing home enforcement area. With respect to the second comment, we believe that intermediate sanctions are an "intermediate step" between no action and the drastic step of termination, yet do not agree that termination necessarily would follow, unless the organization fails to take corrective action in response to sanctions. Our experience generally has been that organizations respond favorably to sanction letters. The commenter's opinion that an intermediate sanction could be worse than termination may be based on a misunderstanding of the nature of the sanction referenced by the commenter. The option of suspending payment for enrollees, under section 1857(g)(2)(C) of the Act, applies only to payments for individuals who enroll after the effective date of the sanction. This sanction option, which is available with respect to the violations specified in §422.752(a), would only apply in a case in which HCFA decided not to impose the sanction of a suspension of enrollment. Finally, the commenter is correct that we view intermediate sanction and civil money penalty authorities as a program management tool that HCFA can employ in the event an organization is not meeting Medicare regulations. Through the use of this tool, HCFA can ensure compliance with regulations without depriving beneficiaries who may be happy with the M+C plan in which they are enrolled of that enrollment option.

Comment: A commenter suggested that HCFA expand intermediate sanctions to include all aspects of grievance and appeals violations.

Response: HCFA has the authority to impose intermediate sanctions for a substantial failure to comply with any grievance and appeal requirement set forth in subpart M. Specifically §422.752(b) provides that HCFA may impose intermediate sanctions for any violation under §422.510(a). Section 422.510(a)(6) in turn specifies a substantial failure to "comply with the requirements in subpart M of this part relating to grievances and appeals" as a sanctionable violation.

P. Medicare+Choice MSA Plans

1. Background

Among the types of M+C options authorized under section 1851(a)(2) of the Act is an M+C medical savings account (MSA) option, that is, a combination of a high deductible M+C insurance plan (an M+C plan) and a contribution to an M+C MSA. Section 1859(b)(3)(A) of the Act defines an MSA plan as an M+C plan that:

- Provides reimbursement for at least all Medicare-covered items and services (except hospice services) after an enrollee incurs countable expenses equal to the amount of the plan's annual deductible.

- Counts for purposes of the annual deductible at least all amounts that would have been payable under original Medicare if

the individual receiving the services in question was a Medicare beneficiary not enrolled in an M+C plan, including amounts that would be paid by the beneficiary in the form of deductibles or coinsurance.

• After the annual deductible is reached, provides a level of reimbursement equal to at least the lesser of actual expenses or the amount that would have been paid under original Medicare, if the individual receiving the services in question was a Medicare beneficiary not enrolled in an M+C plan, including amounts that would be paid by the beneficiary in the form of deductibles or coinsurance.

2. General Provisions (Subpart A)

Sections 422.2 and 422.4 set forth several definitions for terms connected with M+C MSA plans, including "M+C MSA," "M+C MSA plan," and "MSA trustee." We also distinguish between a "network" and a "non-network" M+C MSA plan. These definitions consist of general meanings for these terms as used in the BBA, and do not include specific requirements in the definitions themselves. The definition for an MSA does, however, reference the applicable requirements of sections 138 and 220 of the Internal Revenue Code, while the M+C MSA plan definition references the applicable requirements of part 422.

3. Eligibility, Election, and Enrollment Rules (Subpart B)

a. Eligibility and Enrollment (§422.56)

Any individual who is entitled to Medicare under Part A, is enrolled under Part B, and is not otherwise prohibited (such as an ESRD patient), is eligible to enroll in an M+C plan. However, the statute places several limitations on eligibility to enroll in an M+C MSA plan, and these limitations are set forth at §422.56 of the regulations. Section 422.56(a) indicates that M+C MSA plans are authorized on a limited "demonstration" basis, and incorporates the statutory provisions of section 1851(b)(4), that is:

- No more than 390,000 individuals may enroll in M+C MSA plans.
- No individual may enroll on or after January 1, 2003, unless the enrollment is a continuation of an enrollment already in effect as of that date.
- No individual may enroll or continue enrollment for any year unless he or she can provide assurances of residing in the United States for at least 183 days during that year.

b. Election (§422.62)

Section 1851(e) of the Act establishes general rules concerning the time periods when a beneficiary could elect to enroll in an M+C plan (if one is offered in the beneficiary's area), with special rules for M+C MSA plans set forth at section 1851(e)(5) of the Act. Based on these provisions, §422.62(d)

specifies that an individual may elect an MSA plan only during one of the following periods:

- An initial election period, that is, the 7-month period beginning 3 months before the individual is first entitled to parts A and B of Medicare.
- The annual coordinated election period in November of each year.

4. Benefits (Subpart C)

a. Basic Benefits Under an M+C MSA Plan (§422.103)

Section 422.103 incorporates the statutory requirements for M+C MSA plans defined under section 1859(b)(3) of the Act, as outlined above. Thus, §422.103(a) specifies that an MSA organization offering an MSA plan must make available to an enrollee, or provide reimbursement for, at least all Medicare-covered services (except for hospice services) after the enrollee's countable expenses reach the plan's annual deductible. Further, §422.103(b) then indicates that countable expenses must include the lesser of actual costs or all the amounts that would have been paid under original Medicare if the services were received by a Medicare beneficiary not enrolled in an M+C plan, including the amount that would have been paid by the beneficiary under his or her deductible and coinsurance obligation.

Section 422.103(c) provides that after the deductible is met, an M+C MSA plan pays the lesser of 100 percent of either the

actual expense of the services, or of the amounts that would have been paid under original Medicare if the services were received by a Medicare beneficiary not enrolled in an M+C plan, including the amount that would have been paid by the beneficiary under his or her deductible and coinsurance obligation.

Section 422.103(d), concerning the annual deductible, is based on section 1859(b)(3)(B) of the Act. As the statute specifies, the maximum annual deductible for an MSA plan for contract year 1999 was $6,000. In subsequent contract years, the maximum deductible may not exceed the maximum deductible for the previous contract year increased by the national per capita M+C growth percentage for the year. Thus, based on a national per capita growth percentage of 5 percent, the maximum deductible for 2000 is $6,300. In calculating the maximum deductible for future years, HCFA will round the amount to the nearest multiple of $50.

b. Supplemental Benefits (§§422.102 and 422.104)

Section 422.102 addresses the general M+C rules on supplemental benefits. Unlike other M+C plans, MSA plans are not permitted to include any mandatory supplemental benefits, and are limited in terms of the optional supplementary benefits that can be offered. In accordance with section 1852(a)(3)(B)(ii) of the Act, §422.104(a) specifies that an M+C MSA plan generally may not provide supplemental benefits that cover expenses that count toward the annual deductible. In addition, section 4003(b) of

the BBA added new section 1882 to the Act to prohibit the sale of most supplementary health insurance policies to individuals enrolled in M+C MSA plans. The only exceptions to this rule are spelled out in section 1882(u)(2)(B) of the Act. Further, these exceptions apply both for purposes of the prohibition on selling freestanding supplementary health insurance (or "Medigap" insurance), and for purposes of "optional supplemental benefits" offered under M+C MSA plans. These exceptions are reflected in §422.103(b)(2).

5. Quality Assurance (Subpart D)

Consistent with section 1852(e)(2) of the Act, a network model M+C MSA plan must meet requirements similar to those that apply to all other M+C coordinated care plans (with the exception of the achievement of minimum performance levels); the statute and regulations establish different requirements for non-network M+C MSA plans. These requirements are discussed in detail in section II.D of this preamble.

6. Relationships with Providers (Subpart E)

For the most part, subpart E of new part 422 does not establish any requirements that are specific to MSA plans. However, §422.214, "Special rules for services furnished by noncontract providers," does not apply to enrollees in MSA plans. Section 422.214 implements section 1852(k) of the Act, which contains limits on amounts providers can collect in the case of

coordinated care plan enrollees (section 1852(k)(1) of the Act), and private fee-for-service plan enrollees (section 1852(k)(2) of the Act). As explained in the June 1998 interim final rule preamble, it is clear that Congress intended no such limits to apply to services provided to MSA plan enrollees.

7. Payments Under MSA Plans (Subpart F)

Section 1853 of the Act describes the method to be used to calculate the annual M+C capitation rate for a given payment area. We apply the same methodology in determining the annual capitation rate associated with each M+C MSA plan enrollee, though the actual amount paid to an M+C organization offering an M+C plan is not the amount determined under section 1853 of the Act.

The special rules concerning the allocation of the M+C capitated amount for individuals enrolled in M+C MSA plans are set forth at section 1853. In general, HCFA will allocate the capitated amount associated with each M+C MSA enrollee as follows:

• On a lump-sum basis at the beginning of the calendar year, pay into a beneficiary's M+C MSA an amount equal to the difference between the annual M+C capitation rate calculated under section 1853(c) of the Act for the county in which the beneficiary resides and the M+C MSA premium filed by the organization offering the MSA plan (this premium is uniform for

all enrollees under a single M+C MSA plan, or segment of a plan service area, if authorized under section 1854(h). (See section I.C.7 for a discussion of the BBRA changes in this regard). This results in a uniform amount being deposited in an M+C MSA plan enrollee's M+C medical savings account(s) in a given county, since the uniform premium amount will be subtracted from the uniform county-wide capitation rate for every enrollee in that county.

- On a monthly basis, pay to the M+C organization an amount equal to one-twelfth of the difference, either positive or negative, between the risk adjusted annual M+C capitation payment for the individual and the amount deposited in the individual's M+C MSA.

Section 422.262 contains the regulations concerning the allocation of Medicare trust funds for enrollees in M+C MSA plans.

8. Premiums (Subpart G)

Section 1854 of the Act establishes the requirements for determination of the premiums charged to enrollees by M+C organizations. Like other M+C organizations, organizations offering M+C MSA plans in general must submit by July 1 of each year information concerning enrollment capacity and premiums. For M+C MSA plans, the information to be submitted includes the monthly M+C MSA plan premium for basic benefits and the amount of

any beneficiary premium for supplementary benefits. These requirements are set forth under section 1854(a)(3) of the Act and §422.306(c) of the regulations.

9. Other M+C Requirements

The remaining requirements under subpart 422 have few, if any, implications specific to M+C MSA plans. One issue that we discussed in the interim final rule, however, involves the provision of section 1856(b)(3)(B)(i) of the Act (and §422.402(b)) that any State standards relating to benefit requirements are superseded. We recognize that this provision means that State benefit rules will not apply (for example, State laws that mandate first dollar coverage for particular benefits such as mammograms or other preventative services). Some States may not license entities to offer catastrophic coverage, and it is possible that M+C MSA plans could not be offered in that State. We invited public comment on this issue.

10. Responses to Comments

Comment: We had requested comments on the establishment of a minimum deductible for MSA plans. We had suggested the possibility of establishing the minimum deductible equal to the projected actuarial value of the average per capita copayment under original Medicare. For 1999, that amount would have been $1000. In response, we received three comments. One commenter supported a minimum deductible but recommended that it be higher,

$2000 - $3000. Two other commenters opposed the minimum deductible, stating that it would be counterproductive, and would preclude organizations from offering plans feasible for lower income beneficiaries.

Response: Since that there is neither clear consensus on the issue nor any actual experience under the demonstration, we do not believe it would be appropriate at this time to set a minimum deductible. Therefore, we will continue with only a maximum deductible as specified in the Act, but will include an analysis of the deductible issue in the evaluation of this program.

Comment: One commenter requested clarification of §422.56 specifying how an MSA should be treated in the Medicaid eligibility process.

Response: We are not planning to address the issue of Medicaid eligibility in these regulations. However, this is a valid issue that needs to be addressed in Medicaid eligibility regulations.

Comment: One commenter expressed a concern that MSA enrollees may fail to pay physician claims, based upon experiences with existing deductibles under Medicare. Further, the commenter feared that enrollees might decrease their use of noncovered elective services, such as elective screening and initial diagnostic examinations.

Response: Assuming that an M+C organization chooses to offer an MSA plan, beneficiaries would be advised before they enroll in the plan that they are responsible for initial medical expenses for the year, and each enrollee would have an MSA account to pay at least part of those expenses. Whether they would be able to meet all of their obligations would be considered in the evaluation. The purpose of the M+C MSA program is to permit beneficiaries to play a greater role in their health care purchasing decisions. The program does provide them with incentives to discourage the overutilization of health care services. We had considered requiring first-dollar coverage for services such as certain screening procedures, but decided that would be contrary to the intent of this demonstration.

Comment: One commenter stated that the maximum enrollment of 390,000 beneficiaries would be a disincentive for organizations to participate in the MSA demonstration. This would be too small a number to permit organizations to devote the resources to developing and marketing a high-deductible MSA policy.

Response: The limit of 390,000 enrollees over the course of the MSA demonstration was specified under section 1851(b)(4) of the Act. We are not at liberty to change that requirement by regulation. Nevertheless, as we previously stated, we do not

believe that number would be reached over the course of the demonstration if an M+C organization chose to offer an MSA plan.

Comment: We had solicited comments regarding the issue of whether we should establish sample standardized MSA plans similar to the limited number of Medigap plans. Two organizations commented, both opposing standardized MSA plans as unnecessary and overly restrictive.

Response: We agree with the commenters that there is no need to establish standardized MSA plans under the demonstration.

Comment: Two organizations expressed concern that some States may not license insurers to provide high-deductible policies, thus limiting the availability of MSA plans.

Response: The Act requires that an M+C organization wishing to offer an MSA plan be licensed by the State as a risk-bearing entity, and that the State determine that it can reasonably assume the risk that it would assume under the M+C plan it proposes to offer. It does not require that the organization be licensed commercially to offer a high deductible policy. Therefore, an M+C organization could offer an MSA plan in a State in which the State does not commercially license high deductible plans. The M+C organization must have the State's approval to do so, however.

Comment: Two commenters asserted that the requirement to submit encounter data would be unduly burdensome for M+C

organizations offering MSA plans, particularly for non-network MSA plans. Further, M+C organizations may not have access to claims incurred under the MSA deductible.

Response: This issue was discussed at length during the development of the M+C regulations. Of particular concern was the fact that non-network MSA plans may not see enrollee claims should those claims not exceed the deductible. The possibility of requiring enrollees to submit claims regardless of whether the insurer would have liability was discussed, but dropped as burdensome for enrollees. We believe it is in the interest of the Medicare program that the encounter data submission requirement be maintained for all M+C plans, including MSAs. Should an organization approach HCFA about offering an MSA plan, we would work with the organization on its compliance with these requirements. (For example, enrollees who reach the deductible probably would be required to submit documentation of claims totaling the deductible amount. This documentation might be used to supply encounter data.)

Comment: Four commenters addressed the quality performance measures and the required data submissions. One commenter offered support for the performance improvement projects for MSAs and other M+C plans. Two commenters found the health data requirements for MSAs to be unrealistic, particularly for non-network plans, and likely to deter the offering of MSA and PFFS

plans. A fourth commenter recommended that if certain quality assurance data are not available for certain categories for MSAs and PFFS plans, beneficiaries should be made aware of this lack of information.

Response: M+C organizations offering MSA plans are required by statute to adhere to specified quality standards. Quality performance standards in the June 1998 interim final rule have been modified to accommodate the particular characteristics of an MSA, and the fact that a report will be done on the MSA demonstration (assuming that an M+C organization chooses to offer an MSA plan). We recognize the fact that non-network MSAs may not have access to an enrollee's claims unless that individual's total claims exceed the deductible. In addition, MSAs may not be structured to provide incentives to beneficiaries to obtain preventive and diagnostic services. HCFA is reviewing the quality requirements to make sure that they are feasible for the specific plan for which they are specified.

Comment: One commenter questioned the "community-rated" MSA contributions for all beneficiaries enrolled in an MSA plan, and the lack of balance billing protections for MSA enrollees. Another commenter described the payment methodology as arcane and confusing, and the possibility of a negative premium as absurd.

Response: After lengthy discussions with industry representatives and other officials, the fixed MSA contribution

for all beneficiaries in a specific plan in a specific area seemed to be the approach most consistent with legislative intent. Also, HCFA made a point of clarifying that no balance billing restrictions were included in the statute, and that Congress intended that there be none. As has been previously stated, a negative premium is not impossible, but we would expect an MSA plan to set its premium in a given market at a level to avoid such a possibility.

Q. M+C Private Fee-for-Service Plans

1. Background and General Comments

As noted above, one type of M+C option available under section 1851(a)(2) of the Act is an M+C private fee-for-service (PFFS) plan. Consistent with the statutory definition of an M+C private fee-for-service plan at 1859(b)(2)(A) of the Act, the regulations state that an M+C PFFS plan is an M+C plan that: pays providers at a rate determined by the M+C organization offering the PFFS plan on a fee-for-service basis without placing the provider at financial risk; does not vary the rates for a provider based on the utilization of that provider's services; and does not restrict enrollees' choice among providers who are lawfully authorized to provide the services, and agree to accept the plan's terms and conditions of payment. The requirements M+C organizations must meet to contract with HCFA to offer an M+C PFFS plan generally are incorporated into the relevant sections

of the M+C regulations. An M+C organization wishing to offer a PFFS plan must meet all of the requirements that apply with respect to offering any other type of M+C plan, except to the extent that there are special rules that apply to M+C PFFS plans.

Comment: One commenter contended that HCFA should examine alternatives to the ACR process for ensuring good value under PFFS and MSA plans. The ACR restriction on the premium may conflict with the role envisioned for these plans as paying high fees to providers to ensure unrestricted access.

Response: The commenter is mistaken in the belief that there are restrictions on premiums for M+C MSA and PFFS plans. There is no restriction on the premiums that may be charged for these plans (see §422.306(e)(2)).

Comment: A commenter noted that the regulations create a loosely defined option in which the organization offering a PFFS plan fills in the details of the plan. The commenter questioned whether many beneficiaries would be motivated to join such a plan, whether insurers would be motivated to offer an option that could have such limited appeal. As currently constructed, the commenter believes that M+C PFFS plans are not likely to be viable, and therefore are not likely to be made available to beneficiaries. This in the commenter's view mitigates against the espoused concept of offering a meaningfully expanded range of options. The commenter suggested that HCFA work with the

physician community to do demonstrations to explore what features of the M+C PFFS statute should be changed so that Medicare can offer a viable M+C PFFS defined contribution plan.

Response: We recognize that the statute created a loose structure for M+C PFFS plans, and that therefore M+C plans may vary greatly from one another in how they function. This is a direct consequence of the law. However, we believe that, as currently constituted, M+C PFFS plans are viable. We have received an application for a 30-State, largely rural M+C PFFS plan, and have reason to expect to receive more applications within the next year.

2. Beneficiary Issues

Comment: A commenter objected to the M+C PFFS plan option on the basis that the commenter believes it leaves the beneficiary vulnerable. The commenter's objections included the lack of a quality assurance program to protect beneficiaries, as well as the absence of a cap on premiums or out of pocket expenses, resulting in the possibility that beneficiaries could be charged up to 15 percent over the plan payment amounts. The commenter contended that beneficiaries would be better protected if the PFFS option were not offered.

Response: We recognize that some beneficiary protections provided for under the coordinated care plan option are not included for M+C PFFS plans. In some cases, such as certain

quality assurance requirements, these protections may be less critical in an environment in which the enrollee has complete freedom of choice to use any provider in the country, and is not limited to a defined network of providers. We note that the quality assurance requirements that apply to coordinated care plans do not at this time apply to original Medicare either, which is also a "fee-for-service" arrangement. With regard to the absence of certain limits on beneficiary financial liability, we believe that this makes it particularly important that beneficiaries make a prudent consumer decision when choosing this option. However, we also believe that this alternative can provide a valuable alternative to original Medicare in areas that are not served by coordinated care plans, rural areas in particular. Moreover, we anticipate that, as we gain experience with M+C PFFS contracts, we will determine what changes we need to make to the regulations, or ask Congress to consider improving this M+C option, should we decide that such changes are needed. (We note that we have recently approved the first PFFS plan and intend to monitor its performance closely in order to identify and assess potential beneficiary protection issues.)

Comment: A commenter urged that marketing information to seniors and providers clearly differentiate between traditional Medicare and M+C PFFS plans, as there are substantially different

payment schedules, balance billing rules, and premiums that can be charged for M+C PFFS purposes than for original Medicare.

Response: We agree that there is a significant potential for confusion between original Medicare and the M+C PFFS option, and we have tried to clarify the distinction between these options in our 1999 and 2000 Medicare handbooks (Medicare and You). We are also considering the best way to make this distinction clear in our model explanation of coverage for M+C PFFS plans. The model evidence of coverage document is created for an M+C organization to use as a model for the explanation they provide to beneficiaries about the plan's terms and conditions of coverage. We are currently adapting the existing Evidence of Coverage for coordinated care plans for use in the case of PFFS plans.

Comment: A commenter recommended that we require providers furnishing services to PFFS enrollees and MSA enrollees to give notice if they think the plan may not cover a service. The commenter believes that the same limitations on liability protection that apply in original Medicare should apply to M+C PFFS plans and MSA plan beneficiaries. Moreover, the commenter suggested providers be required to give enrollees of M+C PFFS plans a notice of the expected balance billing amounts that exceed $250 or more (not just the more than $500 notice required of hospitals).

Response: Unlike under original Medicare, the statute does not provide any protection against enrollee or provider liability for services that a M+C PFFS plan determines are not medically necessary to treat illness or injury, and the law does not require providers to give an advance notice to enrollees of the likelihood of plan noncoverage. Therefore, there is no basis in law to require an M+C organization to offer such protection in its plan. Of course, the organization may, if it chooses, build such protection into its plan, and we believe that doing so may be necessary to attract and keep enrollees. Moreover, an enrollee and provider clearly may seek an advance determination of coverage from the M+C organization under the organization determination regulations in part 422 subpart M. Thus, the enrollee and provider have the opportunity to seek a plan determination of coverage before receiving the service, and we encourage them to avail themselves of this option.

With respect to the notice of anticipated cost sharing, the law requires such a notice for hospital services, but not for other services. The M+C organization could, however require that contracting and deemed contracting providers of other types furnish such a notice in advance of providing care as a term and condition of payment, and could set whatever tolerance they chose for such a notice.

We chose the $500 threshold for a notice of out-of-pocket expenses that a hospital may collect from the enrollee because it mirrors the $500 threshold long established by law at section 1842(m)(1) of the Act. Section 1842(m)(1) of the Act requires that a nonparticipating physician who does not accept assignment on the Medicare claim must give the beneficiary advance notice if the actual charges that will be collected from the beneficiary equal or exceed $500. While the benefit to which the threshold applies is different, the concept of advance notice of amounts to be collected from the enrollee is the same, and therefore use of the same threshold is justified.

3. Provider Payment Issues

Comment: A commenter urged that HCFA establish standard payment deadlines, and contended that those for M+C PFFS plans should mirror those for original Medicare.

Response: We believe that the prompt payment provisions of §422.520 largely accomplish this, since they apply to all claims submitted "by, or on behalf of an M+C private fee-for-service enrollee." Since the benefits under a PFFS plan are the enrollee’s benefits, we believe that any claim submitted on behalf of a PFFS plan enrollee is subject to the clean claim standard in §422.520. While written agreements with PFFS plan providers must address this issue, and better terms may be negotiated, we have interpreted the reference to fee-for-service

enrollees in section 1857(f)(1) of the Act to cover all claims involving PFFS enrollees. Under this standard, the M+C organization must pay 95 percent of the "clean claims" within 30 days of receipt, if they are submitted by or on behalf of an enrollee of the M+C PFFS plan, and are not furnished under a written agreement between the M+C organization and the provider. Moreover, the M+C organization must pay interest on clean claims that are not paid within 30 days as required by sections 1816(c)(2)(B) and 1842(c)(2)(B) of the Act for original Medicare.

Comment: A commenter argued that the prompt payment rules at §422.520 permit payers to "game" the clean claim policy by building in a float between the receipt of Medicare payment and the payment to the providers, and recommended that HCFA establish a standard that would apply for PFFS network providers where an organization offering an M+C PFFS plan effectively imposes a delay as a condition of getting the contract.

Response: The prompt payment provisions that apply to all PFFS plan claims ensure against a float of more than 30 days in the case of a "clean" claim.

Comment: A commenter suggested that HCFA require M+C organizations offering PFFS plans to give physicians 30 days notice of changes to fee schedules, and should require them to follow CPT coding conventions in the same manner as original Medicare.

Response: M+C organizations offering PFFS plans must pay noncontracting providers at least the amounts they would receive under original Medicare (less the enrollee's cost-sharing); therefore, there is no potential for changes to the payment rates other than through the annual Medicare fee schedule changes. Also, in order to meet access requirements without having a network in place that satisfies coordinated care plan rules, an M+C organization offering a PFFS plan must pay contracting providers (both those with signed and deemed contracts) at least the Medicare payment rate. In this case, again, providers could count on Medicare payment notices. In all cases, however, providers either will negotiate rates in written and signed contracts, or have the opportunity to learn payment information before providing services under a deemed contract.

4. Noncontracting Provider Issues

Comment: A commenter contended that the regulations should clarify whether a noncontracting provider is precluded from balance billing beneficiaries, and must accept as payment in full rates that are no less than what would be paid under original Medicare. The commenter believes it is not clear: (1) if those rates would include the limiting charge of 115 percent; (2) if noncontracting providers are entitled to direct payment from the M+C organization; or (3) what amounts may be balance billed. The commenter suggested that enhanced balance billing should have

been provided as an incentive to sign a contract, but because of the deemed contract provisions, this basic premise for contracting is lost.

Response: The law permits, but does not require, an M+C PFFS plan to permit contracting providers (with both signed and deemed contracts) to balance bill up to 15 percent of the PFFS plan payment rate for the service, in addition to the cost-sharing established under the plan. The statute expressly applies this to deemed contractors as well. Therefore, the balance billing that an M+C plan may permit contracting and deemed contracting providers to collect will be set by the organization offering the plan. The M+C organization will pay under its terms and conditions of payment, and the contracting or deemed contracting provider may collect the cost sharing and any balance billing permitted by the plan (which cannot exceed 15 percent of the PFFS plan payment rate).

In the case of noncontracting providers (that is, providers that neither have a written contract with the M+C organization offering the PFFS plan nor meet the criteria for a deemed contract), there is no balance billing permitted; by law, the provider may collect no more than the plan's cost sharing. Under section 1852(k)(2)(B) of the Act, the beneficiary liability limits governing payment to noncontracting providers are the same for M+C PFFS plans as for M+C coordinated care plans. We have

clarified this by indicating in §422.214 that the special rules for payment to noncontracting providers that apply for M+C coordinated care plans also apply for M+C PFFS plans. Specifically, the provider must accept as payment in full the amount that it would be entitled to receive under original Medicare, and the plan must pay the provider the amount that the provider would collect if the beneficiary were enrolled in original Medicare, less the enrollee's cost-sharing. For example, if the physician participates in Medicare, the plan would pay the noncontracting physician the Medicare allowed amount less the plan's cost-sharing. In the case of a nonparticipating physician, the plan would pay the Medicare limiting charge less the enrollee's cost-sharing. In the case of an acute care hospital, the plan would pay the diagnosis-related group (DRG) payment less the enrollee's cost-sharing. In the case of a nonparticipating durable medical equipment, prosthetic and orthotics (DMEPOS) supplier, the plan would pay actual charges less the enrollee's cost-sharing.

While the law addresses the payments to providers and the payment liabilities of beneficiaries, it does not specify whether the M+C organization must pay the provider, or whether it may function as an indemnity plan and pay the enrollee, for services for which the enrollee has paid the provider. Moreover, the discussion of prompt payment by M+C plans at section 1857(f) of

the Act contemplates that the M+C organization may make payment to the beneficiary. Hence, the M+C organization may determine to whom (provider or beneficiary) it will make payment for covered services. However, we anticipate that M+C organizations will want to make payment to providers of services, rather than to beneficiaries since we believe that minimizing beneficiary paperwork and confusion is necessary to attract and keep enrollees in the plan.

5. Quality Assurance (§§422.152 and 422.154)

As discussed in section II.D of this preamble concerning quality assurance requirements, M+C PFFS plans and non-network MSA plans (and now PPO plans) are exempt from some of the quality assurance requirements that apply to network model M+C plans. The statute also exempts these plans from external quality review if they do not have written utilization review protocols. As with all other requirements for M+C organizations and M+C plans, those provisions of regulations that are not identified as limited to coordinated care plans or MSA plans also apply to M+C PFFS plans.

Comment: Commenters suggested that §422.154 affirmatively states that M+C organizations, including those offering MSA plans and PFFS plans, must coordinate with an external entity's (that is, a PRO's) investigation of beneficiary quality of care complaints. These commenters believe that beneficiary complaints

are an important indicator of quality of care problems, and that all M+C plans should have to cooperate in investigating them.

Response: The statute relieves an M+C organization offering a PFFS plan of responsibility for contracting for external quality review if it does not carry out utilization review with respect to services covered under the plan.

6. Access to Services (§422.214)

Like other M+C plans, an M+C private fee-for-service plan must offer sufficient access to health care. Section 422.114(a) specifies that an M+C organization that offers an M+C PFFS plan must demonstrate to HCFA that it has sufficient number and range of health care providers willing to furnish services under the plan. Pursuant to the specific instructions of the law, under §422.114(a), HCFA will find that an M+C organization meets this requirement if, with respect to a particular category of provider, the plan has: payment rates that are not less than the rates that apply under original Medicare for the provider in question; contracts or agreements with a sufficient number and range of providers to furnish the services covered under the plan; or a combination of the above. These access tests must be met for each category of service established by HCFA on the M+C organization application. Thus, if an M+C PFFS plan has payment rates that are no lower than Medicare, it need not address if it has a sufficient number of providers of services under written

contract. However, where the plan's payment rates are less than the Medicare payment for that type of provider, the M+C organization must demonstrate that the plan has a sufficient number of providers of that type under written contract.

Medicare payment amounts are established in a variety of different ways. For many of the key services for which Medicare pays, Medicare has prospectively set payment amounts or fee schedules that are established by HCFA and published in the Federal Register each year. These include, but are not limited to, prospective payment systems for acute care hospital services, and skilled nursing care, and fee schedules for physician services (which includes care by many nonphysician practitioners and diagnostic tests), durable medical equipment, and clinical laboratory services. Moreover, HCFA is currently developing prospective payment systems or fee schedules for other key services including home health care, ambulance services, and outpatient hospital care, which we expect to be implemented within the next year or two.

However, for some services, Medicare payments are set retrospectively or concurrently by Medicare carriers and intermediaries. For example, until the prospective payment systems or fee schedules are implemented, home health care, outpatient hospital care, and ambulance services will be paid by carriers and intermediaries based upon a HCFA-specified national

methodology that they apply either upon receipt of the claim (for example, ambulance services paid on a reasonable charge basis) or long after the service is furnished (for example, retroactive cost report settlement). Moreover, there are some services for which reasonable cost and reasonable charge payment will continue indefinitely. Examples of these services are critical access hospital care (which by law must be paid actual cost without limits) and carrier priced physician services (for which the service is too new or too rare to support a national fee schedule value).

Clearly, where there are national prospective payment systems and fee schedules, M+C organizations offering PFFS plans should have no problem in paying amounts no less than the Medicare payment amount for covered services since those amounts are clearly and prospectively published by HCFA. However, the question arises as to how the access test based on Medicare payment levels can be met with regard to services that are paid by Medicare intermediaries or carriers on a reasonable cost or reasonable charge basis. Moreover, consistent with section 1852(d)(4) of the Act and §422.214(b), M+C organizations offering PFFS plans cannot restrict providers from whom the beneficiary can acquire care. Therefore, the M+C organization must have the capacity to pay no less than the Medicare-allowed amounts for any Medicare-covered service furnished by any provider in any area of

the nation. Acquiring the payment amounts from individual Medicare intermediaries and carriers would be a cumbersome and difficult task, and would be likely to result in unwanted payment delays. Therefore, we have decided to permit M+C organizations offering PFFS plans to establish proxies for use in paying services for which no Medicare prospective payment system or fee schedule exists.

The law and regulations permit the use of HCFA-approved proxies as long as those proxies result in payment amounts that are "not less than" Medicare payment rates. If the payment amounts to be paid by the M+C organization are equal to or more than the Medicare payment amounts for those services, the requirement of the law and regulations are met and HCFA must find that the PFFS plan provides for adequate access to care for those categories of services. Therefore, in cases of services for which there is no prospective payment system or fee schedule amount, we will permit M+C organizations to pay proxy amounts under certain circumstances. These proxy amounts must be approved by HCFA as approximating as closely as possible what providers as a whole receive for certain services. Because we expect these payment proxies would be estimates, the M+C organization must also have a process for reviewing these amounts, if necessary, on a provider-by-provider basis. If a provider is able to demonstrate that the proxy amount is less

than the amount Medicare would actually pay, the M+C organization must pay the latter amount.

Proxies will take different forms, depending upon what makes the most sense for the type of service being paid. For example, a hospital that is paid on reasonable costs subject to a limit may be paid a percent of charges that is taken from the provider's last settled Medicare cost report. Similarly, an ambulance supplier may be paid the prevailing charge adjusted for the IC that applies in the year in which the service is furnished. Where proxies are used, HCFA will require that a description of the proxy methodology must be included in the terms and conditions of plan payment for deemed contractors that must be made available to providers of services before they treat an PFFS enrollee (see §422.216(h)(2)(iii)(B)). As nationally established prospective payment systems and fee schedules are developed and implemented by HCFA, the use of proxies should diminish. However, at this time, and for the foreseeable future, for a limited subset of Medicare-covered services, proxies will be necessary for organizations offering M+C PFFS plans that choose not to contract directly with providers. For the reasons discussed above, we believe that their use comports with both the spirit and intent of the law and regulations.

7. Physician Incentive Plans (§422.208)

In §422.208(e), we specify that an M+C PFFS plan may not use capitated payment, bonuses, or withholds in the establishment of the terms and conditions of payment. This is necessary to implement that part of the definition of an M+C plan that specifies that the plan must pay without placing the provider at financial risk.

8. Special Rules for M+C Private Fee-for-Service Plans (§422.216)

As discussed in detail in our June 1998 interim final rule (63 FR 35040), §422.216(a) addresses payment to providers. Specifically §422.216(a)(1) provides that the M+C organization offering a PFFS plan must pay all contract providers (including those that are deemed to have contract under §422.216(f)) on a fee-for-service basis at a rate, determined under the plan, that does not place the provider at financial risk. This reflects the statutory definition of an M+C PFFS plan. We also specify in §422.216(a)(1) that the payment rate includes any deductibles, coinsurance, and copayment imposed under the plan, and must be the same for all providers paid pursuant to a contract whether or not the contract is signed or deemed to be in place. Section 422.216(a)(3) establishes the payment rate for noncontracting providers.

Section 422.216(b) addresses permissible provider charges to enrollees. Under §422.216(b)(1), contracting providers

(including deemed providers) may charge the enrollee no more than the deductible, coinsurance, copayment, and balance billing amounts permitted under the plan. Like payment rates, the plan deductible, coinsurance or copayments and other beneficiary liability must be uniform for services furnished by all contracting providers, whether contracts are signed or deemed to be in place. These two requirements are closely related, since permissible enrollee liability is linked by statute to the plan's payment rate. These cost-sharing amounts must be specified in the plan contract. The plan must have the same cost-sharing for deemed contract providers as for contract providers, and it may permit balance billing no greater than 15 percent of the payment rate for the service.

Other significant requirements set forth in §422.216 address monitoring and enforcement of the payment and charge provisions (§422.216(c)), notifications to plan members concerning payment liability, including balance billing rules (§422.216(d)), and rules covering deemed contract providers, including enrollee and provider notification requirements associated with these providers regarding payment terms and conditions (§§422.216(f), (g), and (h)).

9. Deemed Contracting Providers

Comment: One commenter endorsed having the same standards for deemed and contracting providers so that an M+C PFFS plan

does not become a PPO without the quality assurance standards of a PPO. Other commenters objected to the concept of deemed contracting providers, because they believe that it will reduce provider willingness to provide services in these plans, and because they believe it is unfair to physicians, particularly those who provide emergency care.

Specifically, a commenter indicated that M+C organizations offering PFFS plans will not be able to get providers to sign contracts because there is no incentive for a provider to bind itself to a contract when it is not promised a share of the market in the area, and when it will be paid like a contracting provider, whether it signs a contract or not, under the deemed contracting provisions. Commenters indicated that there will be problems determining the "deemed contract" vs. the noncontract status of providers, since it depends on what they knew at the time of service. A commenter said that HCFA should tighten the rules under which deeming can be presumed, and seek statutory modifications to limit the use of deeming.

Some commenters indicated that emergency department physicians should not be deemed contractors because the M+C organization could blanket an area with terms and conditions of plan payment, and thereby force them to accept terms and conditions with which they did not agree, since they must treat all patients who present in the emergency department. They

commented that HCFA should stipulate that deeming is never presumed to have occurred when emergency services or urgent care are required, particularly when they are required under the Emergency Medical Treatment and Labor Act. Other commenters recommended that the deemed contract language should be amended to explicitly not apply to out of network service provided in an emergency department, and to require that all physicians who provide services in the emergency department be paid as noncontracting providers. Commenters believe that this is needed because, under the Medicare provider agreement anti-dumping rules, the hospital must ensure that all patients who present in the emergency room are seen and that, therefore, the physicians on duty have no ability to choose not to provide care to the enrollee. Under the deemed contracting provisions of the law, they are forced to accept the terms and conditions of plan payment when they treat the patient.

Response: We recognize that the law provides little or no incentive for a provider to sign a contract with an M+C PFFS plan because of the deemed contracting provisions. We also agree that the deemed contracting requirements of the law are problematic, particularly in emergency room settings, and will create disputes between M+C organizations and providers about what the provider knew and when it was known.

The statute specifies that the M+C organization must treat providers that do not have a contract with the plan as if they had such a contract, if the provider knew that the beneficiary was enrolled in the plan, and either knew the terms and conditions of plan payment, or had reasonable access to those terms and conditions.

In general, if the beneficiary has advised the provider of his or her plan enrollment (as is often requested by the provider before providing care), and the provider knows the terms and conditions of plan payment (for example, because the physician or the party to whom the physician has reassigned benefits has received the plan terms and conditions in writing), or has a reasonable opportunity to learn the terms and conditions of plan payment (for example, through a toll free phone number, a website, or by having been sent a copy of the terms and conditions of plan payment), in a manner reasonably designed to effect informed agreement by a provider, then the provider meets the statutory test of being a deemed contracting provider, and the law requires that he or she must be treated as such. The law and regulations presume that, if the provider meets the criteria as a deemed contracting provider and subsequently treats the enrollee, then the provider has implicitly demonstrated agreement to the terms and conditions of payment by treating the enrollee.

While the law does not provide an explicit exception to the deemed provider provisions for emergency or urgent care services, we acknowledge that there are special circumstances that surround services in an emergency department of a hospital that justify considering providers who have not signed a contract with the PFFS plan to be noncontracting providers when they furnish services in an emergency department of a hospital. We have revised §422.216(f) accordingly.

When a physician or hospital has not signed a contract with a PFFS plan but treats a plan enrollee in an emergency department of a hospital, the physician or hospital has no opportunity to refuse to treat the patient as the deemed contracting provisions of the law anticipate. Hence, we believe that it is appropriate to specify that a physician or hospital that furnishes services in the emergency department of a hospital on behalf of the hospital's obligations under the Emergency Medical Treatment and Active Labor Act (EMTALA) cannot be deemed to be a contracting provider. Of course, if the physician or hospital has previously signed a contract with the PFFS plan, the physician or hospital is a contracting provider, and is bound by the terms and conditions of that contract. Moreover, once the services furnished in the emergency department of a hospital cease to be required under §489.24, the criteria that determine whether the

providers are deemed contracting providers or noncontracting providers would then apply.